Complete Summary

GUIDELINE TITLE

New antiretroviral drugs: maraviroc, raltegravir, and etravirine.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. New antiretroviral drugs: maraviroc, raltegravir, and etravirine. New York (NY): New York State Department of Health; 2008 Apr. 4 p. [7 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 12, 2008, Prezista (darunavir): The U.S. Food and Drug Administration (FDA) and Tibotec Therapeutics notified healthcare professionals of changes to the WARNINGS section of the prescribing information for Prezista (darunavir) tablets regarding the risk of hepatotoxicity, specifically, drug induced hepatitis in patients receiving combination therapy with Prezista/ritonavir.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Infectious Diseases
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide guidelines for the use of new antiretroviral drugs maraviroc, raltegravir, and etravirine

TARGET POPULATION

Human immunodeficiency virus (HIV)-infected patients who are treatment-experienced and who have failed to respond to other antiretroviral regimens because of resistance or side effects

INTERVENTIONS AND PRACTICES CONSIDERED

Maraviroc, raltegravir, or etravirine in treatment-experienced patients in combination with at least two fully active agents

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

* Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Committee
- Women's Health Committee
- Substance Use Committee
- Physician's Prevention Advisory Committee
- Pharmacy Committee

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Maraviroc, raltegravir, and etravirine should be used only as part of a new antiretroviral (ARV) regimen in treatment-experienced patients when resistance or side effects have resulted in an inadequate number of other available approved agents. The new regimen should optimally include at least two fully active agents plus the new agent and should be initiated after consultation with a human immunodeficiency virus (HIV) Specialist.

The CCR5 co-receptor antagonist maraviroc should be prescribed only in patients with CCR5-tropic virus, as determined by a tropism assay that is performed at the time that therapy is considered. Maraviroc should not be used outside of clinical trials in patients with dual/mixed- or CXCR4-tropic virus.

The new non-nucleoside reverse transcriptase inhibitor (NNRTI) etravirine should be used only in patients with resistance to previously approved NNRTIs and in combination with one of the following ritonavir-boosted protease inhibitors: lopinavir, darunavir, or saquinavir.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of the new antiretroviral drugs maraviroc, raltegravir, and etravirine

POTENTIAL HARMS

- *Maraviroc*. in side effects include cough, fever, colds, rash, muscle and joint pain, stomach pain, and dizziness. Maraviroc should not be used outside of clinical trials in patients with dual/mixed- or CXCR4-tropic virus.
- *Raltegravir*. Main side effects include rash and diarrhea.
- *Etravirine*. Main side effects: Mild to moderate rash may resolve with continued treatment, but severe rash, including Stevens-Johnson syndrome and erythema multiforme have occurred and require immediate discontinuation. Etravirine should not be administered: 1) with other non-nucleoside reverse transcriptase inhibitors (NNRTIs) and 2) in a protease inhibitor (PI)-containing regimen without ritonavir or with regimens containing tipranavir, fosamprenavir, or atazanavir.

Significant drug interactions can occur between these drugs and concurrent medications. Refer to Table 2, HIV Drug-Drug Interactions, in the "Availability of Companion Documents" field for information on drug interactions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with HIV infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center for providers who lack internet access.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. New antiretroviral drugs: maraviroc, raltegravir, and etravirine. New York (NY): New York State Department of Health; 2008 Apr. 4 p. [7 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Apr

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Medical Care Criteria Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Table 2; HIV drug-drug interactions. New York (NY): New York State Department of Health; 2008 Apr. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

This guideline is available as a Personal Digital Assistant (PDA) download from the New York State Department of Health AIDS Institute Web site.

PATIENT RESOURCES

None available

NGC STATUS

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Date Modified: 11/3/2008


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